

Indiana State Board of Animal Health Report on the Issue of Selling Unpasteurized Milk to Consumers

Prepared for the Indiana General Assembly

11/1/2012

The 2012 Indiana General Assembly directed the Indiana State Board of Animal Health (BOAH) to conduct a study of the issue of farmers selling unpasteurized milk to consumers. The BOAH prepared this Report on the issue in response to the General Assembly's request.

Summary

There is a significant risk that raw milk may contain pathogens. Pasteurization has worked well for many years to reduce substantially the risk of human illness from pathogens that may contaminate milk. The U.S. Food and Drug Administration, U.S. Centers for Disease Control and many other members of the public health community support required pasteurization of milk.

Even with the known risks associated with consuming unpasteurized milk, some consumers are demanding legal access to raw milk. Advocates assert that raw milk tastes better, is more nutritious and healthier. Advocates assert that they should be free to choose pasteurized or unpasteurized milk and that raw milk presents an economic opportunity for farmers.

Currently individuals are acquiring raw milk from producers through cow or herd share arrangements and pet food sales believing that these transactions are outside the current state statute requiring milk to be pasteurized. The current pasteurization statute does not explicitly contemplate these arrangements, creating uncertainty for regulators, producers and consumers as to the legal status of these transactions and arrangements.

Both sides of the raw milk debate have sincere deeply held positions on the issue. No consensus middle ground exists between the public health community that wants no raw milk sales to consumers and advocates who want raw milk sales to consumers.

BOAH believes that pasteurization is a practice that is highly effective in reducing the risk of human illness from pathogens in raw milk. Distributing raw milk for human consumption will increase the risk that someone will become ill from consuming raw milk. But the decision to authorize or not the sale of unpasteurized milk to consumers is ultimately a political decision. BOAH recommends that the Indiana General Assembly consider the following options when considering this issue:

Option A. Maintain the current requirement for milk to be pasteurized prior to sale and amend the statute to clarify that all persons producing milk for consumption must comply with state sanitation standards and pasteurize the milk regardless of the method used to distribute the milk, including cow or herd share arrangements and products labeled for pet food.

Option B. Change the current law requiring pasteurization to allow limited distribution of raw milk directly from the farmer producing the milk to consumers and authorize the BOAH to establish minimum sanitary requirements that may reduce the risk of human illness.

If Indiana is to move away from the current laws requiring pasteurization of milk and milk products sold to the public, the following principles should be followed:

1. The Indiana State Board of Animal Health should have the authority to adopt rules requiring permits and establishing sanitation standards for raw milk producers.
2. All farmers producing raw milk for consumption should be held to the same standards.
3. The sale of raw milk should be limited to the farmer producing the milk selling directly to consumers.

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Introduction

The 2012 Indiana General Assembly adopted House Enrolled Act 1129 (HEA 1129). HEA 1129 includes non-code provisions requiring the Indiana State Board of Animal Health (BOAH) to **“conduct a study of the issue of farmers selling unpasteurized milk to consumers.”** The Act requires BOAH to prepare a report setting forth the results of the study not later than December 1, 2012.ⁱ

BOAH has conducted a study of the issue of unpasteurized milk sales and has prepared this document to report the agency’s findings.

Study Process

In this report the BOAH has attempted to compile, summarize and represent information surrounding the arguments for and against selling raw milk to consumers. In preparing this report, BOAH collected information and ideas from many sources through the following processes:

BOAH Research. BOAH conducted research and compiled information on the issue in the following areas:

- Background information.
- Public health information.
- Raw milk advocates’ information.
- How other states and countries have addressed the issue.

Advisory Committee. BOAH convened a volunteer advisory committee to study the issue of selling raw milk to consumers in Indiana. The Committee included representatives from many dairy interests with a varied set of experiences and knowledge. A list of the committee members is included in **Appendix A**. The Committee included members who were in favor of allowing raw milk sales to the public and members who opposed raw milk sales to the public. BOAH asked the Committee to put aside their opinions on whether or not raw milk sales should be legalized and consider the question: “If there were to be an Indiana program for the sale of raw milk, what should the program include?” The Committee’s consensus thoughts and conclusions on that question are included in **Appendix B**.

Virtual Public Hearing. BOAH initiated a method to allow any member of the public to provide information or comments via a “virtual public hearing”. The hearing began on June 1 and ended on September 1. Comments were submitted via the BOAH website or mailed to the agency. The BOAH received 831 comments via the virtual public hearing. The comments included 789 comments from Indiana residents. The BOAH did not view this process as a

referendum vote on whether or not raw milk should be allowed. BOAH's intent was to gather as many ideas as possible on the issue to inform the study. The people who submitted comments did not disappoint and provided many valuable ideas that informed the writing of this report.

Dairy Farm Survey. BOAH conducted a survey of state-permitted dairy farms to collect dairy farmers' opinions on the raw milk for consumption issue. In the survey, BOAH attempted to gather some information on how many current licensed dairy farms would be interested in selling raw milk for consumption if it were legal in Indiana. BOAH received 242 survey responses, a 15.8% response rate. Of the farmers who responded, 158 indicated they would sell raw milk to consumers if it was legalized in Indiana. Of the respondents who reported they would not sell raw milk to consumers if legalized, 34% cited liability concerns and 30% cited concerns with maintaining their relationship with their current cooperative.

The Indiana Dairy Industry

A complete discussion of the make-up and economic impact of the Indiana dairy industry is beyond the scope of this report. A brief summary of the Indiana dairy sector includes the following:

- There are approximately 176,000 dairy cows in Indiana on 1527 dairy farms.
 - These cows produce 3.4 billion pounds of milk per year, or 300 million pounds per month.
 - This production places Indiana 14th in the rank of states by total milk production.
 - Indiana's is home to 36 dairy processing plants that make a wide array of products.
- Indiana ranks number 2 among states in the production of low-fat ice cream in the U.S.

Indiana Dairy Law

The State of Indiana has regulated the production of milk and dairy products since at least the 1920s. In 1925 the Indiana General Assembly passed a law requiring pasteurization of milk or tuberculin testing of cattle.ⁱⁱ The Milk Control Act was enacted on March 12, 1935.ⁱⁱⁱ The Indiana Supreme Court ruled the Act was constitutional on March 26, 1936.^{iv}

The current Indiana dairy inspection program is governed by the Indiana State Board of Animal Health. Ind. Code § 15-17-2-8 and Ind. Code § 15-18-1. The state dairy law requires a permit from BOAH prior to operating a dairy farm, milk plant, receiving or transfer station, milk tank truck or bulk milk hauler, or a milk container manufacturing facility. Ind. Code § 15-18-1-3.

The BOAH is authorized to adopt rules governing standards for the production of milk and milk products. Ind. Code 15-18-1-14. BOAH currently recognizes two grades of milk and milk products: Grade A and manufacturing grade.

Grade A milk is milk produced at a farm holding a Grade A dairy farm permit and meets the standards for Grade A milk. Grade A milk products are those produced at a plant holding a Grade A dairy plant permit. Grade A milk products must be made from Grade A milk and must meet the standard for Grade A products. There are many types of Grade A products, such as fluid milk, yogurt and various dairy ingredients. 345 IAC 8-2-1.5. **In Indiana, 1275 farms currently hold a Grade A dairy farm permit and 15 dairy plants holding a Grade A dairy plant permit.**

BOAH is required to adopt rules to establish standards for Grade A milk and milk products that are at least as effective in protecting public health as the standards adopted by the National Conference on Interstate Milk Shipments (NCIMS). IC 15-18-1-14 and 345 IAC 8. The NCIMS is a body made up of representatives from each state and the U.S. Food and Drug Administration. Farmers, processors, academia and advocacy groups also participate. The NCIMS cooperates with the U.S. Food and Drug Administration through a memorandum of understanding. The NCIMS conducts a conference every two years to establish and modify Grade A standards. The NCIMS standards are published in the Pasteurized Milk Ordinance (PMO) that provides the model standards for states to utilize when governing the production of Grade A milk and milk products. The NCIMS recently published a 2011 revision of the PMO.^v

Manufacturing grade raw milk is milk produced on a dairy farm that does not have a Grade A dairy farm permit or otherwise does not meet the standard for Grade A raw milk. Manufacturing grade milk products are milk products that are not Grade A, such as cheese, butter, ice cream and other frozen desserts. 345 IAC 8-2-1.1(a)(29)-(30). The BOAH has established standards for manufacturing grade dairy farms and manufacturing grade dairy plants. 345 IAC 8-2-2 through 345 IAC 8-2-3. **In Indiana, 252 farms currently hold a manufacturing grade dairy farm permit and 21 dairy plants hold a manufacturing grade dairy plant permit.**

The state dairy statute requires pasteurization of milk for human consumption. The state dairy law prohibits the offering, display for sale, selling, delivering or possession with the intent to sell or deliver milk or milk products for human consumption unless “every particle of the final mixture of the milk or milk products used in processing manufacture has been thoroughly pasteurized by equipment approved by the board.” Ind. Code § 15-18-1-21(a). A copy of this section is included in **Appendix C**.

The pasteurization requirement applies to Grade A and manufacturing grade milk and milk products. However, the pasteurization requirement does not apply to certain cheeses manufactured from raw milk if the cheeses are manufactured and aged in accordance with the statute and rules adopted by the BOAH. Ind. Code § 15-18-1-21(b) and 345 IAC 8-3-1(e).

The Indiana dairy inspection program at BOAH has a long-standing policy interpreting the pasteurization law not to apply to a dairy farmer utilizing unpasteurized milk from his or her farm in his or her household, for members of his or her household, and non-paying guests.

United States Food and Drug Administration Regulation

The U.S. Food and Drug Administration (FDA) prohibits the interstate sale of raw milk for human consumption through a regulation adopted in 1987. The FDA rule governs only the interstate sale of unpasteurized milk to consumers. Each state governs the intrastate sale of unpasteurized milk to consumers.

The FDA regulation was adopted after a series of events beginning in 1973 that culminated in a decision issued by the United States District Court for the District of Columbia that ordered the FDA to “approve a rule banning the interstate sale of all raw milk and all raw milk products, both certified and non-certified”.^{vi} The published opinion includes a recounting of the history of the FDA rule. A copy of the opinion is included in **Appendix D**.

The current FDA regulation includes the following prohibition:

Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.

(a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties. 21 CFR § 1240.61(a).

A copy of the entire regulation is included in **Appendix E**.

The FDA has stated publicly an enforcement policy for the pasteurization regulation. The FDA states it has never initiated an enforcement action against individuals who transport raw milk across state lines solely for personal consumption and that it has no present intent to do so. The FDA maintains it will only enforce the regulation against persons who produce and/or distribute unpasteurized milk in interstate commerce. **Appendix F**.

There have been several recent attempts to modify or overturn the FDA regulation:

1. An on-line petition was submitted to the Office of the White House requesting support to modify the FDA regulation. The Office of the White House denied the request in February 2012. **Appendix G**.
2. Two bills were introduced into the 112th United States Congress to overturn the FDA regulation.^{vii} **Appendix H**. Congress did not act on either bill.

3. The Farm-to-Consumer Legal Defense Fund filed a lawsuit challenging the constitutionality of the FDA regulation. This action was dismissed by the United States District Court for the Northern District of Iowa on March 30, 2012.^{viii} The suit was dismissed on the grounds that the plaintiffs lacked standing because there was no injury in fact because the FDA made it “abundantly clear” that the FDA has not and does not intend to enforce the regulations against “an individual who purchased and transported raw milk across state lines solely for his or her own personal consumption”.^{ix}

The FDA has engaged in recent activity to enforce their interstate rule:

In February 2012 the FDA obtained a permanent injunction preventing a farmer holding a Pennsylvania license to sell unpasteurized milk to consumers from transporting his unpasteurized products across state lines.^x **Appendix I.**

News reports indicate the FDA has recently investigated a Northern Indiana farm for alleged violations of the FDA regulation.^{xi} **Appendix J.**

What is Pasteurization?

Pasteurization is the process of exposing a food to an elevated temperature for a period of time sufficient to destroy certain microorganisms without radically altering the food.^{xii}

For the production of milk and dairy products, pasteurization standards are established by the U.S Food and Drug Administration (FDA) by regulation.^{xiii} Pasteurization is further defined by the states through the NCIMS process and states’ adoption of the Pasteurized Milk Ordinance (PMO) standards.^{xiv}

The pasteurization standards for milk and milk products require heating every particle of milk and milk product in properly designed and operated equipment to a temperature for a designated time. Recognized time, temperature and equipment combinations are set forth in rules. Other time, temperature and equipment processes may be recognized by the Food and Drug Administration as meeting the pasteurization requirements if the FDA determines them to be equally efficient in the destruction of microbial organisms of public health significance.^{xv}

The pasteurization standards further define specific processes such as:

“ultra-pasteurization” that produces a product with extended shelf-life under refrigerated conditions; and

“aseptic processing” that produces a product to maintain commercial sterility under normal unrefrigerated conditions.^{xvi}

Pasteurization virtually eliminates pathogens in milk. Pasteurized milk must be handled appropriately, such as maintaining refrigeration, to prevent reintroduction and growth of bacteria that may contaminate the product.

History of Pasteurization

Raw milk was recognized as a source of severe infections more than 100 years ago. Pasteurization of milk to prevent these infections is considered one of the public health triumphs of the 20th century.

In 1938, milkborne illness outbreaks constituted twenty-five percent of all disease outbreaks due to infected foods and contaminated water. Today milk and fluid products are associated with less than one percent of such reported outbreaks.^{xvii} The reduction in the number of milkborne illnesses over this time reflects the implementation of improvements in many areas including the following:

- i. Programs to control animal diseases, such as brucellosis, tuberculosis and mastitis;
- ii. Enhanced farm sanitation practices;
- iii. Temperature control of milk products from the farm to the consumer; and
- iv. Pasteurization of the majority of commercial dairy products.^{xviii}

Routine pasteurization of milk began in the 1920s and became widespread in the United States by 1950 as a means to reduce contamination and resulting illness. This led to dramatic reductions in diseases previously associated with milk. Many public health experts consider pasteurization to be one of public health's most effective food safety interventions.^{xix}

A chart summarizing the history of pasteurization is included in **Appendix K.**^{xx}

The Argument for Pasteurizing Milk.

The U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC) have repeatedly issued warnings that raw milk may harbor dangerous microorganisms that can pose serious health risks to people. Appendix L. The proponents of pasteurization and prohibiting raw milk sales make the following points^{xxi}:

1. Unpasteurized milk can carry dangerous organisms that are a threat to the public's health.
 - Unpasteurized milk can carry dangerous bacteria, such as *Salmonella enterica*, *E. coli* O157:H7, *Campylobacter jejuni* and *Listeria monocytogenes*, which are responsible for causing numerous foodborne illnesses.

- In recent years, pathogenic microorganisms have been isolated in bulk milk tank samples at rates ranging from 0.87% to 12.6% of total samples collected, indicating a measurable probability of encountering pathogenic bacteria in raw milk.^{xxii}
 - Harmful bacteria in raw milk can seriously affect the health of anyone who drinks raw milk, or eats foods made from raw milk. The bacteria in raw milk can be especially dangerous to pregnant women, children, the elderly, and people with weakened immune systems.
 - Getting sick from raw milk can mean many days of diarrhea, stomach cramping, and vomiting. Most healthy people will recover from an illness caused by harmful bacteria in raw milk.
 - Some people who become ill from harmful bacteria in raw milk can develop symptoms that are chronic, severe, or even life-threatening. Such illnesses can lead to kidney failure, paralysis, chronic disorders, and even death. For example, a person can develop Guillain-Barré syndrome, which can cause paralysis and hemolytic uremic syndrome that can result in kidney failure and stroke.
 - Raw milk does not kill dangerous pathogens by itself.
2. Milk may be contaminated on the farm in any of the following ways:
 - Cow feces coming into direct contact with the milk.
 - Infection of the cow's udder (mastitis).
 - Animal diseases. Animals that shed organisms capable of causing disease in humans in the animal's milk, such as bovine tuberculosis and brucellosis.
 - Bacteria that live on the skin of cows.
 - Bacteria in the environment (e.g., feces, dirt, processing equipment).
 - Insects, rodents, and other animal vectors.
 - Humans, for example, by cross-contamination from soiled clothing and boots.
 3. Adherence to good hygienic practices during milking can reduce, but not eliminate, the risk of milk contamination.
 - The dairy farm environment is a reservoir for illness-causing organisms.
 - No matter what precautions farmers take, they cannot guarantee that their milk or the products made from their milk are free of harmful organisms.
 - Even if tests of raw milk for pathogens are negative, there is no guarantee that the milk does not contain harmful organisms.
 - Animals that carry harmful pathogens usually appear healthy.
 4. Pasteurization of milk is an effective method for reducing the public health risk of pathogenic organisms in raw milk.

- Pasteurization does kill harmful bacteria.
 - Pasteurization kills harmful organisms responsible for diseases such as listeriosis, typhoid fever, tuberculosis, diphtheria, and brucellosis.
 - Pasteurized milk contains low levels of the type of nonpathogenic bacteria that can cause food spoilage, so storing pasteurized milk in the refrigerator is still important. It is not safe to leave milk out of the refrigerator for extended time, particularly after it has been opened.
 - Pasteurization does save lives.
 - Preventing food-borne illnesses saves tax money that would otherwise be spent on investigating food-borne illness outbreaks and treating victims.
5. Pasteurization does not reduce milk's nutritional value.
- Research shows no meaningful difference in the nutritional values of pasteurized and unpasteurized milk.
 - Pasteurized milk is rich in proteins, carbohydrates, and other nutrients. Heat slightly affects a few of the vitamins found in milk: thiamine, vitamin B12, and vitamin C, but milk is only a minor source of these vitamins.
 - Pasteurizing milk does not cause lactose intolerance and allergic reactions. Both raw milk and pasteurized milk can cause allergic reactions in people sensitive to milk proteins.
 - Pasteurization has helped provide safe, nutrient-rich milk and cheese for more than 120 years.

Numerous organizations support pasteurizing milk and prohibiting the sale of unpasteurized milk to consumers. The following organizations have issued statements taking this position on the subject:

American Association of Food and Drug Officials
 American Association of Public Health Veterinarians
 American Medical Association
 American Veterinary Medical Association
 Association of Food and Drug Officials
 Cornell University Food Science Department
 Indiana State Medical Association
 International Dairy Foods Association
 International Association for Food Protection (IAFP)
 National Environmental Health Association
 National Mastitis Council
 National Milk Producers Federation

Appendix M.

Food Borne Illness Outbreaks and Raw Milk

Unpasteurized milk may contain pathogenic organisms. But has raw milk made people sick? **Recent studies and reports indicate that people have become sick from consuming raw milk.**

Pasteurization, correctly applied, eliminates pathogens in milk. However, from time-to-time outbreaks of human illness are associated with pasteurized milk and milk products due to post-pasteurization contamination. If a person may become sick from consuming pasteurized milk and may become sick from consuming unpasteurized milk, is there additional risk from consuming unpasteurized milk?

Scientists associated with the Centers for Disease Control (CDC) compile data on disease outbreaks. The CDC has analyzed dairy-associated disease outbreak occurrences and reports the following:

States that allow the legal sale of raw milk for human consumption have more raw milk-related outbreaks of illness than states that do not allow raw milk to be sold legally.

Among dairy product-associated outbreaks reported to CDC between 1973 and 2009 in which the investigators reported whether the product was pasteurized or raw, 82% were due to raw milk or cheese. From 1998 through 2009, 93 outbreaks due to consumption of raw milk or raw milk products were reported to CDC. These resulted in 1,837 illnesses, 195 hospitalizations, and 2 deaths. Most of these illnesses were caused by *Escherichia coli*, *Campylobacter*, or *Salmonella*. It is important to note that a substantial proportion of the raw milk-associated disease burden falls on children; among the 93 raw dairy product outbreaks from 1998 to 2009, 79% involved at least one person younger than 20 years old.^{xxiii}

A study released by CDC in February 2012 examined the number of dairy outbreaks in the United States during a 13-year period. Between 1993 and 2006, 60% (73/121) of dairy-related outbreaks reported to CDC were linked to raw milk products. Three-quarters of these outbreaks occurred in states where the sale of raw milk was legal at the time. Experts also found that those sickened in raw milk outbreaks were 13 times more likely to be hospitalized than those who got ill from pasteurized milk during an outbreak.^{xxiv}

A copy of this CDC article is included in **Appendix N**.

The CDC data on pasteurized and unpasteurized dairy-associated outbreaks has been compiled by the working group associated with the website www.realrawmilkfacts.com. Copies of these tables are included in **Appendix O** of this report.^{xxv}

Proponents of raw milk consumption argue that the incidence of foodborne illness from dairy products, whether pasteurized or not, is extremely low. They accuse the CDC of using data selectively and misinterpreting data to make raw milk look dangerous by:

1. Focusing on outbreaks rather than the number of people who became ill and the severity of the illness.
2. Aggregating incidences of raw milk and raw milk products rather than identifying certain raw milk products, such as non-aged queso fresco raw milk cheese, that have caused a greater number of illnesses thereby distorting the safety of raw milk.
3. Underestimating the number of Americans who consume raw milk to distort the statistics.

^{xxvi} **Appendix P.**

The Argument for Unpasteurized Milk and Opposition to Pasteurization

Proponents of unpasteurized milk consumption argue that raw milk provides benefits to consumers and farmers and is no more risky than other food products. Proponents make various claims about the dangers of pasteurizing milk. Not all proponents of raw milk agree on all aspects of the pro-raw milk argument. The following is a list of arguments various proponents have advanced in favor of consuming unpasteurized milk^{xxvii}:

1. Raw milk contains beneficial properties and pasteurizing milk changes or destroys these properties.
 - Raw milk has a higher content of butterfat.
 - Raw milk has no additives.
 - Pasteurization destroys or inactivates enzymes in raw milk.
 - Pasteurization destroys the following properties of raw milk: B-lymphocytes, macrophages, neutrophils, lymphocytes, IgA/IgG antibodies, B12 binding protein, bifidus factor, medium-chain fatty acids, fibronectin, gamma-interferon, lactoferrin, lactoperoxidase, lysozyme, mucin A/Oligosaccharides, hormones and growth factors.
 - Pasteurization denatures proteins in raw milk.
 - Pasteurization destroys vitamins such as C, B12, and B6.
 - “Good” bacteria are destroyed through heat treatment (pasteurization). Good bacteria inhibit the growth of pathogens. Therefore, pasteurization leads to an increased risk of pathogens in milk.
2. Consuming raw milk cures or is beneficial to the treatment of certain conditions and consuming pasteurized milk causes or exacerbates certain conditions.
 - Consuming raw milk prevents or aids in the treatment of allergies, tooth decay, colic (infants), osteoporosis, arthritis, heart disease and cancer.
 - Pasteurization can worsen the symptoms of asthma and allergies.
 - Pasteurization causes lactose intolerance.
 - Raw milk helps people develop a strong immune system.

- Raw milk has healing powers.
 - Raw milk is not homogenized. Homogenization is linked to heart disease.
 - Raw milk has a probiotic effect.
3. Pasteurization does not guarantee safe milk. Pasteurization does not completely eliminate the risk of pathogens in milk. Pasteurization does not protect against the risk of all diseases that may be spread through milk. Some risk is associated with pasteurized milk and some risk is associated with raw milk. Therefore, pasteurized milk should not be required and unpasteurized milk should not be prohibited.
- There have been outbreaks of human illness from pasteurized milk.
 - The sale of raw milk has been authorized in some states and countries for decades providing a track record of production that is not perfect, but compares favorably to the safety record of other foods.
4. Advancements in technology have solved the problems that led to the requirement for milk pasteurization.
- Management of the herd and the milking process determine the safety of milk. Pasteurization was developed a long time ago at a time when animal health and farm sanitation were inadequate for the production of safe raw milk. Dairy farms are different now and pasteurization is no longer needed because of the following developments:
- Modern materials such as stainless steel are utilized to handle and store milk.
 - Advances in equipment technology, such as milking machines as opposed to hand milking, protect against contamination of milk.
 - Refrigeration of bulk tanks and refrigerated transportation provide readily available methods for safer storage and handling of raw milk.
 - Advances in sanitation technology and methods reduce the risk of milk contamination.
 - Advances in animal health and nutrition have reduced the risk of disease transfer from cows through milk. Advocates routinely link the safety and nutrition of raw milk to feeding cows grass through grazing as opposed to feeding grain.
 - Advances in testing for diseases and pathogens in animals, water and milk provide effective tools that can be used to manage the risk of pathogens in milk.
5. The sale of raw milk can save small family farms and promote rural development.
- The demand for raw milk is an opportunity for small dairies to produce a product and sell it to consumers at a price that is profitable, rather than selling their raw milk to a processor for pasteurization at a lower price.
6. Consumers should have the freedom to choose to drink raw milk even if there are risks.
- People should be free to choose what they eat without interference from government.

- Consumers may legally buy other raw foods that may carry pathogens, such as raw meat, raw chicken, raw eggs, raw fish, raw oysters, raw spinach, raw lettuce and more.
- Raw milk is as safe or safer than other foods that are commonly purchased raw.
- Raw milk tastes better.
- The benefits of raw milk outweigh the risks.

Demand for Raw Milk

Some Indiana consumers want unpasteurized milk. The extent of Indiana consumers' demand for unpasteurized milk is not known. Farmers and consumers have engaged in various schemes to obtain unpasteurized milk. BOAH is aware that each of the following schemes have been and are likely currently being utilized in the state to distribute unpasteurized milk to consumers:

Direct Sales

Some consumers may obtain raw milk directly from a farmer without regard for the current legal prohibition on raw milk sales.

Pet Food Sales

The Office of the Indiana State Chemist (OISC) at Purdue University implements the Indiana Commercial Feed Law.^{xxviii} The Feed Section of the Office of the Indiana State Chemist regulates commercial animal feeds, including pet and specialty pet food manufactured or distributed in Indiana. The OISC reports increased interest in farmers obtaining a commercial feed license to sell unpasteurized milk and milk products made from unpasteurized milk as animal food.

The Indiana State Board of Animal Health, the OISC, and local health departments have reported an increase in recent years in the number of retail stores and booths at farmers markets selling unpasteurized milk and milk products labeled as animal food. Some of these sales have been accompanied by literature or other promotions urging unpasteurized milk be used for human consumption.

In 2012 the Indiana General Assembly enacted amendments to Indiana Code 15-19-7-40 to require distribution of raw milk for use as commercial feed with a prominent label stating "Not for Human Consumption". The amendments further prohibited promoting or advertising animal feed as suitable for human consumption unless the products have met all legal requirements to be sold as human food.^{xxix}

The American Veterinary Medical Association recently issued a policy discouraging the feeding of any animal-source protein to cats and dogs that has not first been subjected to a process to eliminate pathogens because of the risk of illness to cats and dogs as well as

humans. The AVMA statement includes feeding raw milk from a different species to a dog or cat.^{xxx} **Appendix Q.**

Cow and Herd Shares

The Indiana dairy inspection program at BOAH has a long-standing policy interpreting the pasteurization law not to apply to the owner of a dairy farm utilizing unpasteurized milk in his or her household for members of his or her household and non-paying guests. Some proponents of unpasteurized milk have sought to exploit this policy to find a way to obtain “legally” unpasteurized milk. The types of schemes undertaken vary case-by-case but are often referred to as “cow share” or “herd share” arrangements.

Indiana has no uniform definition of what a cow share and herd share arrangement means. Many share arrangements involve the consumer signing a document that purports to transfer partial ownership of a cow, some cows, or an entire herd to the consumer. The agreement often specifies the quantity of milk the consumer may expect to receive from his or her share in the cow(s) or herd. The consumer pays money to the farmer for the share. Most agreements require an ongoing payment by the consumer to the farmer for the farmer to board the cow(s) and for the service of milking the cow(s) and bottling the milk for the consumer.

State and federal officials have successfully challenged some cow and herd share arrangements as merely disguised sales that are prohibited by state or federal pasteurization statutes.^{xxx} Other states have been only partially successful or unsuccessful in their challenges to cow and herd share arrangements.^{xxxii} A small number of states have explicitly authorized cow and herd share arrangements.^{xxxiii} The Indiana dairy inspection law^{xxxiv} does not directly address the issue and the issue has not been litigated in Indiana.

Distribution Agreements

Farmers and consumers have attempted to circumvent the pasteurization requirement by distributing unpasteurized milk using numerous variations of farm-centric distribution channels. Examples include:

A community supported agriculture (CSA) program where consumers purchase a membership or subscription that entitles them to a share of the farm’s production.

Buying clubs where consumers order products directly from the farm. The products may be delivered by the farmer or picked up by consumers.

The reasoning used to justify unpasteurized milk distribution in this manner varies. Often the claim includes the idea that these distribution channels are closed or limited to members only; therefore, state regulations, including the pasteurization requirement, do not apply.

Insurance for Product Liability Risk

Farmers selling unpasteurized milk to consumers are exposed to the risk that they will be held liable for injuries to consumers should customers become sick from their product. Is it possible for Indiana farmers to insure against the risk from liability resulting from selling raw milk?

The Indiana Department of Insurance reported to the BOAH the following concerning insurance coverage availability for liability resulting from the sale of raw milk products as of May 14, 2012:

“Neither of the two largest property and casualty insurance bureaus have filed raw milk exclusion forms in Indiana. One of the bureaus indicated that they are monitoring the issue and plan to explore it further. The other bureau indicated that they make available sample endorsements to affiliates (subscribers) to assist with the development of custom or independent forms, although they have not developed sample exclusionary language applicable to liability resulting from a virus, bacterium or other microorganism that is within or on any products intended for human consumption.

There are 5 insurance carriers that represent approximately 75% of the Farmowners market in Indiana. Of the top 5 carriers writing Farmowners coverage in Indiana (by Farmowners written premium reported), 2 exclude coverage for raw milk liability and 3 do not.

The largest Farmowners carrier (by written premium) does have a raw milk exclusion in their Farmowners program, which accounts for nearly half of the Indiana marketplace.

Insurer #1 – Market Share 46.75% - Raw Milk Exclusion
Insurer #2 – Market Share 15.60% - No Raw Milk Exclusion
Insurer #3 – Market Share 4.57% - No Raw Milk Exclusion
Insurer #4 – Market Share 4.45% - No Raw Milk Exclusion
Insurer #5 – Market Share 4.01% - Raw Milk Exclusion

As bureau forms excluding liability for raw milk exposures are not generally available to insurance carriers in Indiana at this point in time, insurers who wish to eliminate or reduce this exposure are filing independent exclusion forms or reducing their exposure through underwriting practices.”^{xxxv}

Intrastate Sales of Raw Milk in Other States

The National Association of State Departments of Agriculture (NASDA) conducted a survey of the states concerning the regulation and sale of raw milk to consumers. The reported survey results indicate that twenty states prohibit the sale of unpasteurized milk to consumers, including Indiana. The report indicates thirty states authorize the sale of unpasteurized milk to consumers in some manner.^{xxxvi} **Appendix R.**

The states that allow the sale of unpasteurized milk to consumers regulate production and sale of the milk in various ways attempting to influence the risks associated with the practice. BOAH conducted a review of state laws governing the sale of unpasteurized milk to consumers and found that state regulations vary widely across the country.

There is no standardized method utilized by the states to regulate the production or sale of unpasteurized milk to consumers. But, almost all of the states that allow unpasteurized milk sales limit access to raw milk and regulate the production and sale of the product. The following is an outline of different methods utilized by states to regulate unpasteurized milk sales. A copy of a summary created by BOAH of various state law provisions is included in **Appendix S** of this report.

Regulations affecting where and how unpasteurized milk is sold.

Nearly all of the states that allow the sale of unpasteurized milk prohibit resale of the product and prohibit the sale of raw milk in restaurants, hotels, schools, health care facilities and other institutions.

Eighteen of the thirty states that authorize the sale of raw milk to consumers restrict sales to the farm where the milk was produced. Many states authorizing on-farm sales impose additional restrictions on sales, such as:

- Four states limit sales to goat milk only.
- Four states restrict sales to “incidental sales” only.
- A minority of states authorizing on-farm sales permit the farmer to deliver product direct to the consumer.

Twelve of the thirty states that authorize the sale of raw milk to consumers allow sales at retail stores and farmers markets in some manner. Some states authorizing retail sales impose additional restrictions on sales, such as restricting sales to stores owned by the farmer and restricting sales to goat milk only.

A minority of states have explicitly addressed cow or herd share arrangements. The states that have addressed these arrangements are split between those that exempt the arrangements from some regulations and states that treat the arrangements no differently than any other farm producing raw milk.

Many of the states authorizing raw milk sales restrict sales in other ways, such as the following:

A majority of states allow the sale of milk or milk and cream only, prohibiting the sale of milk products (butter, yogurt, etc.) made from unpasteurized milk.

A minority of states restrict the number of animals that may be milked or the volume of product that may be sold.

Licensing and Inspections

Nearly all of the states that allow the sale of unpasteurized milk to consumers require the farmer producing and packaging the milk to obtain a permit from the state and undergo sanitary inspections.

Minimum Sanitary Requirements

Most states authorizing the sale of unpasteurized milk to consumers have established standards for farmers to meet in the following areas:

- Cow health
- Milking parlor construction and sanitation
- Equipment construction and sanitation
- Milk quality, microbial and contamination standards and testing programs (somatic cell count, bacteria, coliform, pathogens, and drug residues)
- Cooling temperatures and storage
- Milk plant construction and sanitation
- Containers, filling and capping
- Labeling, including warning labels on containers and signage.

Regulation of Raw Milk Sales in Other Countries

The BOAH did not attempt to conduct a comprehensive survey of the raw milk laws in other countries. The BOAH did accumulate some information on the following countries:

Canada

Federal law prohibits the sale of raw milk to consumers.

European Union

Member states are able to introduce or maintain national rules prohibiting or restricting sales of raw milk or raw cream intended for direct human consumption.

England and Wales

The United Kingdom Food Standards Agency reviewed the raw cow milk policy between 1997 and 1999 and concluded that the balance of stakeholder opinion was strongly in favor of the right to informed choice. The Agency revisited its raw milk policy in 2002 and concluded that relatively few people drink raw milk and those who do, do so regardless of the exiting health warnings. The Agency concluded that the most balanced approach would be to maintain the existing regulatory policy. The policy includes the following:

- Raw milk may be sold directly to consumers by registered milk production facilities, at the farm gate, in a farmhouse catering operation, through milk deliverymen or at farmers markets. Sales through other outlets have been banned since 1985.
- Herd health standards must be met.
- Producers of raw milk must comply with hygiene rules.
- Products must contain a health warning.
- Products are sampled and tested. ^{xxxvii}

Scotland

Raw milk and raw cream intended for direct human consumption is prohibited. The ban for cow milk has been in place since 1983 and was extended to include all milk in a January 2006 regulation. ^{xxxviii}

Italy

Since 2004, raw milk sales are allowed by local officials in territories. Italy formally authorized vending machine sales through automatic vending devices in 2007. Raw milk sales are regulated.

Germany

Raw milk sales from the farm are legal. Sales off of the farm and through vending machines allowed with additional regulation.

Conclusion

Both sides of the raw milk debate have sincere deeply held positions on the issue. No consensus middle ground exists between the public health community that wants no raw milk sales to consumers and advocates who want raw milk sales to consumers.

There is a significant risk that raw milk may contain pathogens. Pasteurization effectively eliminates pathogens from milk therefore substantially reducing the risk that people will become ill from consuming milk containing pathogens. Passing a law allowing the sale of unpasteurized milk will likely lead to an increase in the number of farmers selling unpasteurized milk to consumers, an increase in the volume of unpasteurized milk sold to consumers and an increase in the number of people consuming raw milk. With more people exposed to greater volumes of unpasteurized milk, the risk that someone will become ill from consuming milk that contains pathogens will increase. Therefore, changing Indiana law to allow the sale of unpasteurized milk will increase the risk that consumers will become ill from consuming pathogens in unpasteurized milk.

The U.S. Food and Drug Administration has evaluated the risks associated with selling unpasteurized milk to consumers, decided the risks outweigh the benefits, and has acted to prohibit the sale of unpasteurized milk to consumers in interstate commerce.

Twenty states have evaluated the risks associated with selling unpasteurized milk to consumers, decided the risks outweigh the benefits, and have acted to prohibit the sale of unpasteurized milk to consumers within their states.

Thirty states have evaluated the risks associated with selling unpasteurized milk to consumers and decided to allow access to raw milk in some manner within their states. Almost all of these states limit consumer access to raw milk and regulate the production and distribution of raw milk in a manner designed to reduce, but not eliminate, the risks associated with unpasteurized milk.

BOAH Recommendations

Pasteurization has worked well for many years to reduce substantially the risk of human illness from pathogens that may contaminate milk.

Even with the known risks associated with consuming unpasteurized milk, some consumers are demanding legal access to raw milk. BOAH cannot quantify this demand. Currently individuals are acquiring raw milk from producers through cow or herd share arrangements and pet food sales believing that these transactions are outside the current state statute requiring milk to be pasteurized. The current pasteurization statute does not explicitly contemplate these arrangements, creating uncertainty for regulators, producers and consumers as to the legal status of these transactions and arrangements.

BOAH believes that pasteurization is a practice that is highly effective in reducing the risk of human illness from pathogens in raw milk. Distributing raw milk for human consumption will increase the risk that someone will become ill from consuming raw milk. But the decision to authorize or not the sale of unpasteurized milk to consumers is ultimately a political decision. BOAH recommends that the Indiana General Assembly consider the following options when considering this issue:

Option A. Maintain the current requirement for milk to be pasteurized prior to sale and amend the statute to clarify that all persons producing milk for consumption must comply with state sanitation standards and pasteurize the milk regardless of the method used to distribute the milk, including cow or herd share arrangements and products labeled for pet food.

Option B. Change the current law requiring pasteurization to allow limited distribution of raw milk directly from the farmer producing the milk to consumers and authorize the BOAH to establish minimum sanitary requirements that may reduce the risk of human illness. If Indiana is to move away from the current laws requiring pasteurization of milk and milk products sold to the public, the following principles should be followed:

4. The Indiana State Board of Animal Health should have the authority to adopt rules requiring permits and establishing sanitation standards for raw milk producers.
5. All farmers producing raw milk for consumption should be held to the same standards.
6. The sale of raw milk should be limited to the farmer producing the milk selling directly to consumers.

ENDNOTES

ⁱ House Enrolled Act 129.1.43 includes the following non-code provision:

SECTION 43. [EFFECTIVE UPON PASSAGE] (a) **As used in this SECTION, "board" refers to the Indiana state board of animal health established by IC 15-17-3-1.**

(b) **The board shall conduct a study of the issue of farmers selling unpasteurized milk to consumers.**

(c) **The study required by subsection (b) must be concluded before November 1, 2012.**

(d) **At the conclusion of the study, the board shall prepare a report setting forth the results of the study not later than December 1, 2012. The board shall:**

(1) **present the report to:**

(A) **the governor; and**

(B) **the legislative council in an electronic format under IC 5-14-6; and**

(2) **make copies of the report available to the public.**

(e) **This SECTION expires June 30, 2013.**

ⁱⁱ *Public Health in Indiana*, The Indiana Historian, Indiana Historical Bureau, <http://www.in.gov/history/2917.htm> (last visited September 21, 2012) .

ⁱⁱⁱ Acts of 1935, Chapter 281, p. 1365.

^{iv} *Alvert et al. v. Milk Control Board of Indiana*, 210 Ind. 283; 200 N.E. 688 (1936).

^v The PMO is available online at the following site: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/default.htm>

^{vi} *Public Citizen v. Heckler*; 653 F. Supp. 1229 (D.D.C. 1986)

^{vii} H.R. 1830, 112th Cong., 1st Sess. (2012) and S. 1955, 112th Cong., 2d Sess. (2012)

^{viii} *Farm-to-Consumer Legal Defense Fund v. United States Department of Health and Human Services*; No. 5:10-cv-04018 (N. D. Iowa, filed Feb. 20, 2010)

^{ix} *Farm-to-Consumer Legal Defense Fund v. United States Department of Health and Human Services*; No. 5:10-cv-04018, 2012 U.S. Dist. LEXIS 46290, at 2 (N. D. Iowa. March 30, 2012)

^x *United States of America v. Daniel L. Allgyer*; No. 11-02651 (E. D. PA, February 2, 2012).

^{xi} Roger Schneider, *Middlebury Dairy Farmer, Sheriff Stand up to FDA*, Goshen News, December 17, 2011.

^{xii} "pasteurization" *Merriam-Webster.com*. Merriam-Webster, 2012. Web. 28 March 2012.

^{xiii} 21 C.F.R. § 1240.61 (2011)

^{xiv} 345 IAC 8-2-1.7

^{xv} 21 C.F.R. § 1240.61(d) (2011)

^{xvi} 345 IAC 8-2-1.7(d) and (e)

^{xvii} U.S. Department of Health and Human Services, Public Health Service and Food and Drug Administration. 2011. Grade “A” Pasteurized Milk Ordinance. 2011 Revision. Available at:
<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/default.htm>

^{xviii} Position Statement on Raw Milk Sales and Consumption, Cornell University Food Science Department, available at: <http://foodscience.cornell.edu/cals/foodsci/extension/milk-quality-improvement-program.cfm#Factsheets>

^{xix} Letter from Robert Tauxe, MD, MPH, Deputy Director, Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, to State and Territorial Epidemiologists and State Public Health Veterinarians (July 18, 2012)(on file with the Indiana State Board of Animal Health).

^{xx} Adapted from information on the web site: <http://www.idfa.org/news--views/media-kits/milk/milestones>

^{xxi} Compiled from various sources, including the following:

Comments submitted to the Indiana State Board of Animal Health during a virtual public hearing held between Jun 1, 2012 and September 1, 2012.

U.S. Food and Drug Administration documents on raw milk are available at the following web sites:
<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ucm277854.htm>

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/ConsumerInformationAboutMilkSafety/default.htm>

U.S. Centers for Disease Control and Prevention documents on raw milk are available at the following web site:
<http://www.cdc.gov/foodsafety/rawmilk/raw-milk-index.html>

Position Statement on Raw Milk Sales and Consumption, Cornell University Food Science Department, available at <http://foodscience.cornell.edu/cals/foodsci/extension/milk-quality-improvement-program.cfm>

Raw milk Legislation Packet, Real Raw Milk Facts (July 2012), <http://www.realrawmilkfacts.com/legislation-packet/>

^{xxiii} <http://www.cdc.gov/Features/RawMilk/>

^{xxiv} Adam J. Langer, ET AL., Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws- United States, 1993-2006, *Emerging Infectious Diseases Journal*, Vol. 18, No.3, March 2012, available at www.cdc.gov/eid,

^{xxv} <http://www.realrawmilkfacts.com/outbreak-tables>

^{xxvi} Press Release, The Weston A. Price Foundation, CDC Cherry Picks Data to Make Case Against Raw Milk, (February 22, 2012)

^{xxvii} Compiled from various sources, including the following: Comments submitted to the Indiana State Board of Animal Health during a virtual public hearing held between Jun 1, 2012 and September 1, 2012; www.realmilk.com; <http://www.thecompletepatient.com/>; www.raw-milk-facts.com.

^{xxviii} Indiana Code 15-5-3.

^{xxix} P.L.99-2012

^{xxx} *Raw or Undercooked Animal-Source Protein in Cat and Dog Diets*, American Veterinary Medical Association (July 2012), <https://www.avma.org/KB/Policies/Pages/Raw-or-Undercooked-Animal-Source-Protein-in-Cat-and-Dog-Diets.aspx>

^{xxxi} *United States of America v. Daniel L. Allgyer*; No. 11-02651 (E. D. PA, February 2, 2012).

^{xxxii} *State Appeal Dropped in Raw Milk Investigation*, AP March 21, 2007, available in LEXISNexis, AP State and Regional Wires – Ohio Stories.

^{xxxiii} Colorado Revised Statutes 25-5.5-117 (2011); Idaho Administrative Code 02.04.13.008 (2011)

^{xxxiv} Ind. Code 15-18-1.

^{xxxv} E-mail from Kate E. Kixmiller, Deputy Commissioner, Indiana Department of Insurance to Doug Metcalf, Chief of Staff, Indiana Board of Animal Health (May 14, 2012, 11:31 AM)(on file at the BOAH).

^{xxxvi} Ehart, Bob. “NASDA Releases Raw Milk Survey.” www.nasda.org. July 19, 2011.

^{xxxvii} *Raw drinking milk and raw cream control requirements in the different countries of the UK, May 11 2009*, <http://www.food.gov.uk/business-inidustry/guidancenotes/hygguid/rawmilkcream> (last visited July 16, 2012).

^{xxxviii} *Id.*